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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,215	02/25/2004	Hugh S. West JR.	14000.8.1.2	3044
7590 08/13/2007 John M. Gynn WORKMAN, NYDEGGER & SEELEY 1000 Eagle Gate Tower 60 East South Temple Salt Lake City, UT 84111			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 08/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/786,215

Applicant(s)

WEST ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 11-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11 state "In a graft tensioning device for use in joint repair surgery, a suture pulley assembly adapted...comprising: ". It appears that these claims are intended to be written as Jepson style claims. As such, it is unclear what is being claimed (i.e. a graft tensioning device and a suture pulley assembly, or a suture pulley assembly only). If these claims are to be written as Jepson style claims, they must contain the phrase "...the improvement comprising..." in the preamble (MPEP 2129). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (US Pat. 4,950,271) in view of Fletcher (US Pat. 3,869,932).

Lewis et al. disclose, in a graft tensioning device for use in joint repair surgery, a suture pulley assembly adapted so as to receive one or more looped sutures of varying size and equalize tension on both sides of the looped sutures (Fig. 2, ref. 50), the suture pulley assembly comprising: a rotatable pulley wheel (Fig. 2, ref. 57) (column 5, lines 58-61) comprising first (Fig. 1, left side of ref. 57) and second pulley plates (Fig. 1, right side of ref. 57); attaching means (Fig. 2, unlabeled post through ref. 57) for rotatably attaching said pulley wheel to an adjustable tension applicator of the graft tensioning device (Fig. 2, ref. 57)(column 5, lines 58-61), said pulley plates of said pulley wheel thereby rotating independently of the adjustable tension applicator when equalizing tension between each side of a looped suture. The attachment means comprising a post (Fig. 2, post through ref. 57) that passes through a central recess of each pulley plate and that is attached at a first end to the adjustable tension applicator of the graft tensioning device. The post is fixedly attached to the adjustable tension applicator (Fig. 2). The post further comprising a flange at a second end opposite said first end and adjacent to one of said pulley plates, said flange overlapping at least a portion of an outer surface of said pulley plate adjacent to said flange (Fig. 2, ref. 56). A graft tensioning device (Fig. 1, ref. 40) for use in joint repair surgery, comprising a suture pulley assembly as defined in claim 1 (Fig. 2, ref. 50); and at least one adjustable tension applicator (column 6, lines 51-60) to which said suture pulley wheel of said suture pulley assembly is rotatably attached (Fig. 2, ref. 57)(column 5, lines 58-61) and which is configured to apply a desired tensile load to a looped suture attached to free ends of a looped tissue graft, said suture pulley assembly being adapted for equalizing

a tensile load applied by said adjustable tension applicator to each side of the looped suture. The graft tensioning device comprising two independently adjustable tension applicators (Fig. 2, refs. 50) and a separate suture pulley (Fig. 2, central ref. 50) assembly as defined in claim 1 rotatably attached to each of said two independently adjustable tension applicators (Fig. 2).

Lewis et al. disclose, in a graft tensioning device for use in joint repair surgery, a suture pulley assembly (Fig. 2, ref. 50) adapted so as to receive one or more looped sutures of varying size and equalize tension on both sides of the looped sutures, the suture pulley assembly comprising: a rotatable pulley wheel (Fig. 2, ref. 57)(column 5, lines 58-61) comprising first (Fig. 1, left side of ref. 57) and second pulley plates (Fig. 1, right side of ref. 57). The first and second pulley plates having inner surfaces that define said pulley space (Fig. 2, place where ref. 57 sits). The post is fixedly attached to the adjustable tension applicator (Fig. 2). The post further comprising a flange (Fig. 2, ref. 56) at a second end opposite said first end and adjacent to one of said pulley plates, said flange overlapping at least a portion of an outer surface of said pulley plate adjacent to said flange.

Lewis et al. disclose a graft tensioning device for use in joint repair surgery, comprising: at least one adjustable tension applicator (Fig. 2, ref. 40) configured to apply varying tensile loads to a looped suture attached to free ends of a looped tissue graft; and a suture pulley assembly (Fig. 2, ref. 50) attached to said adjustable tension applicator and adapted so as to transmit varying tensile loads from said adjustable tension applicator to the looped suture, said suture pulley assembly comprising: a pulley

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wheel (Fig. 2, ref. 57)(column 5, lines 58-61) rotatably attached to said adjustable tension applicator and comprising first (Fig. 1, left side of ref. 57) and second pulley plates (Fig. 1, right side of ref. 57), a post (Fig. 2, unlabeled post through ref. 57) attached at a first end to said adjustable tension applicator, said post passing through a central recess of each of said first and second pulley plates so as to rotatably (column 5, lines 58-61) attach said pulley wheel to said adjustable tension applicator and allow said pulley plates to rotate independently of said adjustable tension applicator when equalizing tension between each side of a looped suture.

Lewis et al. does not disclose the pulley plates having a variable distance therebetween which sized and positioned so as to define a variable pulley space for accepting therein at least one looped suture; and biasing means for biasing at least one of said pulley plates toward the other of said pulley plates in order for said pulley space defined by the distance between said first and second pulley plates to selectively increase or decrease in cross-sectional width as the distance between said pulley plates increases or decreases in response to insertion of differently sized sutures into said pulley space; a spring positioned relative to at least one of said first and second pulley plates so as to bias at least one of said pulley plates toward the other of said pulley plates in order for said pulley space defined by said distance between said first and second pulley plates to selectively increase or decrease in cross-sectional width as the distance between said pulley plates increases or decreases in response to insertion of differently sized sutures into said pulley space; at least a portion of said inner surfaces of said first and second pulley plates being angled so that at least a portion of said

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pulley space has decreasing width from an outer perimeter of said pulley plates toward a center of said pulley wheel; a portion of said pulley space nearest said center of said pulley wheel having a constant width. The suture assembly further comprising a sleeve disposed around at least a portion of said post between said post and an inner edge of each pulley plate defining said central recess. The spring being disposed around a portion of said sleeve. The suture pulley assembly further comprises a washer disposed between said spring and the adjustable tension applicator of the graft tensioning device. Lewis discloses that having a more precise and repeatable length adjustment of the ligament graft or graft components is desirable (abstract).

Fletcher discloses a pulley wheel (Fig. 1) with two pulley plates (Fig. 1, refs. D and E) having a variable distance therebetween (column 1, lines 15-19) which is sized and positioned so as to define a variable pulley space; a biasing means (column 1, lines 19-22, e.g. the leaf springs); the spring at least a portion of said inner surfaces of said first and second pulley plates being angled (Fig. 1, angled surfaces of refs. 60 and 62); a spring (column 1, lines 19-22, e.g. the leaf springs) positioned relative to at least one of said first and second pulley plates so as to bias at least one of said pulley plates toward the other of said pulley plates in order for said pulley space defined by said distance between said first and second pulley plates to selectively increase or decrease in cross-sectional width (column 1, lines 19-22). A portion of said pulley space nearest said center of said pulley wheel having a constant width (Fig. 1, portion near refs. 50 and 52). The device includes a sleeve (Fig. 1, ref. B) and a washer (Fig. 1, ref. 24). This type of pulley wheel allows for the varying of the drive ratio (column 1, lines 19-22).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the pulley wheel of Lewis et al. having a variable distance between the pulley plates and utilizing a spring as a biasing means as taught by Fletcher in order to allow the device of Lewis et al. to vary the drive ratio (column 1, lines 19-22), in order to realize the predictable result of allowing a surgeon to more precisely and repeatably adjust the length and tension of a graft. By altering the drive ratio of the pulley wheel of Lewis et al. the surgeon would be better able to have a more precise and repeatable length adjustment of the ligament graft or graft component. For example, if a surgeon needed to substantially adjust the length of the ligament, the drive ratio could be altered to allow a small turn of the wheel to effect a large change in the length and tension of the ligament. If a very small, very precise change in length and tension is required, the surgeon would be able to adjust the drive ratio so that a small turn of the wheel would effect a small change in the length and tension of the graft.

Response to Arguments

Applicant's arguments filed 04/27/2007 have been fully considered but they are not persuasive.

With regard to the Applicant's argument that there is no motivation to combine the references, the Examiner notes that it has been held that the rigid application of the "teaching, suggestion, or motivation" test, under which patent claims are proved obvious only if the prior art, the nature of problem addressed by inventor, or the knowledge of person having ordinary skill in art reveals some motivation or suggestion to combine

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prior art teachings, is inconsistent with the expansive and the flexible "functional approach" to the resolution of the obviousness issue, under which the scope and content of the prior art are determined, the differences between the prior art and claims at issue are ascertained, the level of ordinary skill in pertinent art is resolved, and secondary considerations such as commercial success, long felt but unsolved needs, and failure of others may be considered if doing so would prove instructive; the rigid TSM approach is therefore rejected. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

With regard to Applicant's argument that the periphery of the device of Lewis et al. in view of Fletcher would not be unobstructed and would not allow a surgeon to place a looped structure around the wheel, the Examiner respectfully disagrees. The outer periphery of the wheel can be considered to be unobstructed as claimed, since the flexible suture could be wrapped around the wheel and touch all points of the outer periphery when wrapped around the wheel. In other words, since the suture is capable of bending, the wheel will be unobstructed with respect to the suture, since the suture can reach all points along the periphery of the wheel, since it can bend around the portions of the graft tensioning device that otherwise may obstruct the periphery.

With regard to Applicant's argument that the wheel of Lewis in view of Fletcher is not positioned or designed to receive a looped structure, it is noted that the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). The device of Lewis in view of Fletcher is capable of allowing a

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looped suture to be received on it; the looped suture could be placed on the wheel in the same manner as non-looped suture (e.g. wrapped around the wheel).

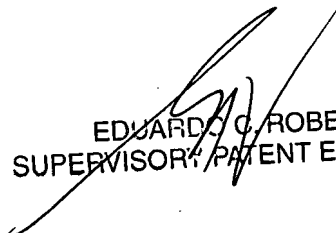
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC


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